Supreme Court, U.S.
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No. 93-

IN THE

Supreme Court of the United States

October Term, 1993

JAMES ALBERT ELKINS, SR.; MARY JO ELKINS, as parents and natural guardians of JAMES ALBERT ELKINS, II,

Petitioners,

v.

RICHARDSON-MERRELL, INC.,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a party may legitimately move for summary judgment under Fed. R. Civ. P. 56(c) based not on "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any" referenced by that rule, but instead based simply on the conclusory assertion that the non-moving party does not have sufficient evidence to support its case.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Sixth Circuit (**A1-A9**[1]) is reported at 8 F.3d 1068. The opinion of the United States District Court for the Middle District of Tennessee (**A10-A13**) is unreported. The Report and Recommendation of the Magistrate Judge (**A14-A16**), recommending a grant of summary judgment, is unreported.

JURISDICTION

The decision of the court of appeals issued on October 20, 1993. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

PROCEDURAL RULE INVOLVED

Rule 56(c) of the Federal Rules of Civil Procedure provides, in relevant part:

> **Rule 56. Summary Judgment**
>
> **(c) Motion and Proceedings Thereon**. . . . The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. . . .

STATEMENT OF THE CASE

This Petition presents a square conflict in the circuits over the proper interpretation of *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), concerning the burden facing a movant for summary judgment under Rule 56(c) of the Federal Rules of Civil Procedure. The Sixth Circuit, which affirmed the summary judgment below, reads *Celotex* as permitting a party to "move for summary judgment *asserting* that the opposing party will not be able to produce sufficient evidence at trial to withstand a

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[1] Page references to the appendices to this Petition are styled "**A**__."

directed verdict motion," and thereby to "challenge the opposing party to '*put up or shut up*' on a critical issue," so that if the opponent "[does] not 'put up,' summary judgment [is] proper." *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1478 (6th Cir. 1989) (emphasis added). *See also* **A5-A6**; pp. 4-5, *infra*.

Other circuits have rejected this approach. The Eleventh Circuit, for example, has noted that *Celotex* is "commonly misunderstood and misapplied," and has held that "[e]ven after *Celotex* it is never enough simply to state that the non-moving party cannot meet its burden at trial." *Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 607-08 (11th Cir. 1991). The Fifth Circuit has followed suit, praising the "thorough opinion" in *Clark* as exposing "a common misunderstanding of [*Celotex*]." *Russ v. International Paper Co.*, 943 F.2d 589, 591 (5th Cir. 1991), *cert. denied*, 112 S. Ct. 1675 (1992). The Fourth Circuit has also rejected the "put up or shut up" approach to summary judgment. *See Higgins v. Scherr*, 837 F.2d 155, 156-57 (4th Cir. 1988) ("the non-movant [is] not required to prove his entire case upon the mere incantation by [the movant] of 'summary judgment'").

This petition seeks review of this conflict among the circuits on a fundamental aspect of federal civil procedure.

1. Trial Court Proceedings. This is a products liability case falling under diversity jurisdiction and governed by Tennessee law. Petitioner James Albert Elkins, II was born on April 23, 1969, without legs, and missing portions of his right upper arm. Suit was filed on his behalf in the United States District Court for the Middle District of Tennessee, alleging that his limb defects had been caused by Bendectin, a prescription anti-nausea drug that was marketed by respondent Richardson-Merrell, Inc. ("Merrell"), which his mother took during the limb-development phase of her pregnancy. **A10**.

Merrell filed a motion for summary judgment, stating that "plaintiff cannot establish that Bendectin is capable of causing birth defects in general" and therefore that plaintiff could not

establish causation.[2] Rule 56(c) provides that summary judgment motions are decided on "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any." The only item on this list referenced by Merrell was the affidavit of an epidemiologist who, after analyzing a variety of epidemiological data, stated that "[b]ased upon these analyses, it is my opinion to a reasonable degree of medical and scientific certainty that maternal Bendectin ingestion is not associated with, and does not cause, limb reduction defects."[3]

Elkins opposed summary judgment on the strength of affidavits from several concededly qualified experts who had reached the conclusion, on this issue of general causation, that Bendectin *is* capable of causing birth defects. The district court, while assuming the admissibility of Elkins' evidence, granted summary judgment on the basis of two intervening Sixth Circuit decisions in cases with similar records, both concluding that the analysis contained in these experts' affidavits was insufficient to prove causation.[4]

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[2] Memorandum of Law in Support of Defendant Merrell Dow's Motion for Summary Judgment, dated June 21, 1991, at 3 (Sixth Cir. Joint Appendix ("**JA**") **70**).

[3] Affidavit of Dr. Steven H. Lamm, dated May 28, 1991, ¶ 10(e) (**JA 109**).

[4] After the summary judgment motion was briefed in the district court, the Sixth Circuit affirmed grants of summary judgment in Bendectin cases with similar records. *See Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992); *Lee v. Richardson-Merrell, Inc.*, No. 91-5369, 1992 U.S. App. LEXIS 8478 (6th Cir. April 22, 1992), *cert. denied*, 113 S. Ct. 197 (1992). On the strength of *Turpin* and *Lee*, the district court held that Elkins' expert affidavits on causation were insufficient to defeat summary judgment. *See* **A11-A12**. The Sixth Circuit agreed with this holding, **A2-A5**, a point on which Elkins does not now seek review in this Court.

2. The Decision on Appeal. While this case was pending on appeal, this Court handed down its decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), addressing the rules for admissibility of expert scientific testimony. In relevant part, *Daubert* mandated that the testimony of a scientific expert is not admissible under Fed. R. Evid. 702 unless the expert demonstrates that the "reasoning or methodology underlying the testimony is *scientifically valid*." *Id.* at 2796 (emphasis added).

Elkins argued to the Sixth Circuit, in a supplemental brief and at oral argument, that summary judgment must be reversed because the sole record support cited by Merrell in its motion — the affidavit by its epidemiologist — was clearly inadmissible under *Daubert* on the record of this case.[5] Therefore, Elkins argued, Merrell had never met its burden of production under Rule 56(c) to "show" the court through reference to *some* material in the record that no genuine issue existed, so that it was left with the mere *conclusory assertion* that "plaintiff cannot establish that Bendectin is capable of causing birth defects in general." *See* p. 2, *supra*. Elkins cited *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970), and *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986), as both holding that a non-movant has no obligation to respond unless and until the movant makes the required "show[ing]" by reference to record material.[6]

The Sixth Circuit took note of this argument and assumed that Merrell's sole affidavit could be found inadmissible under

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[5] *See* Letter Brief, dated July 26, 1993, at 1-5. Specifically, Elkins pointed out that the affidavit of Merrell's expert made no attempt to validate the methodology the expert had used, and that four of Elkins' experts had affirmatively attacked the methodology of Merrell's expert — that of relying *only* on epidemiological data to determine the risks posed by Bendectin, and ignoring three other types of data — as completely invalid. *Id.* at 3-4. For example, one expert stated: "it is *scientifically improper* to rely solely upon epidemiology studies to determine whether or not a drug is a teratogen." *Id.* at 4 (emphasis added) (quoting **JA 301**). Merrell made no response, either in writing or at oral argument, to this detailed demonstration of the invalidity of the methodology used by its only expert.

[6] *See id.* at 4-5 & n.1.

Daubert, but nevertheless held that Elkins had "misinterpreted the defendant's burden regarding summary judgment." **A5**. According to the Sixth Circuit, under Rule 56(c) a movant need *not* "show" the court the materials in the record demonstrating the absence of a genuine issue; it need only "point out the lack of a genuine issue" through a conclusory assertion to that affect. **A5-A6**. As support for the idea that such an assertion forces the non-movant to prove its case, the Sixth Circuit cited Rule 56(b) permitting motions to be made "with or without supporting affidavits" and, most critically, this Court's statement in *Celotex* that

> regardless of whether the moving party accompanies its summary judgment motion with affidavits, the motion may, and should, be granted so long as whatever is before the district court demonstrates that the standard for the entry of summary judgment, as set forth in Rule 56(c) is satisfied.

Celotex, *supra*, 477 U.S. at 323. *See* **A5**.

"Because Merrell does not bear the ultimate burden of persuasion on the causation issue," the court below held, Merrell had no burden to "show" the court anything in the record in order to win summary judgment under Rule 56(c):

> The reason for summary judgment was not the strength of the defendant's proof, but the insufficiency of the plaintiffs' proof. Thus, the admissibility of Merrell's affidavit under *Daubert* is irrelevant; the district court properly determined that the *plaintiffs* failed to demonstrate the existence of a genuine factual dispute regarding causation. The plaintiffs bear the burden of establishing causation. As a result, *Daubert* does not invalidate the district court's summary judgment analysis in this case.

A6 (emphasis in original).

REASONS FOR GRANTING THE WRIT

Review is warranted in this case to put an end to what the Fifth and Eleventh Circuits have correctly described, in detailed and cogent opinions, as a common misunderstanding of this Court's *Celotex* opinion: the idea that a conclusory assertion that the non-movant cannot win is enough to force the non-movant to "put up or shut up" and prove its case. Instead these circuits, along with the Fourth Circuit, cite the opinions of eight Justices in *Celotex* as making clear that the basic rule of *Adickes* remains unchanged: the movant must "show" from the sources listed in Rule 56(c) that no genuine issue appears to exist, based on the materials in the record. *See* cases cited at p. 2, *supra*; *see also United States v. Four Parcels of Real Property*, 941 F.2d 1428, 1437-38 & nn. 19-20 (11th Cir. 1991); *Fano v. O'Neill*, 806 F.2d 1262, 1266 (5th Cir. 1987).

The core holding of *Celotex*, on which eight Justices agreed, was that a movant is not necessarily required to file affidavits in order to "show" the absence of a genuine issue.[7] The only

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[7] *Celotex* clarified the nature of the moving party's burden by explaining that under Rule 56(c), if the moving party can establish its factual proposition "solely on the 'pleadings, depositions, answers to interrogatories, and admissions on file'" (the first four sources listed in Rule 56(c)), the moving party need not also produce an affidavit (the final source of proof listed in Rule 56(c)). *See* 477 U.S. at 324 (majority opinion) ("[i]n cases like the instant one, where the nonmoving party will bear the burden of proof at trial on a dispositive issue, a summary judgment motion may properly be made in reliance solely on the 'pleadings, depositions, answers to interrogatories, and admissions on file'") (quoting Rule 56(c)). *See also id.* at 328 (White, J., concurring) ("I agree that the Court of Appeals was wrong in holding that the moving defendant must *always* support his motion with evidence or affidavits . . . [and] I also agree that the movant may rely on depositions, answers to interrogatories, and the like, to demonstrate that the plaintiff has no evidence to prove his case and hence that there can be no factual dispute") (emphasis added); *id.* at 334 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting) ("I agree with the Court that . . . Celotex could seek summary judgment on the ground that plaintiff could not prove exposure to Celotex asbestos at trial").

Justice Stevens did not reach the issue of a movant's initial burden under Rule 56(c), arguing instead for an affirmance on a narrow factual ground and criticizing the views of the other eight Justices as an "abstract exercise in Rule construction." 477 U.S. at 339 (Stevens, J., dissenting).

disagreement among these Justices was about "the application of [Rule 56(c)'s framework] to the facts of this case." 477 U.S. at 334 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting).

To be sure, the majority opinion in *Celotex* did observe, in a passage cited by the Sixth Circuit below, that summary judgment should be decided based on "whatever is before the district court," arguably suggesting that a conclusory assertion is enough to satisfy a party's Rule 56(c) burden. *See id.* at 323; p. 5, *supra*. In conflict with that interpretation, however, is the statement at the beginning of the same paragraph that, "[o]f course, a party seeking summary judgment always bears the initial responsibility of . . . identifying those portions of the [record] which it believes demonstrate the absence of a genuine issue of material fact." *Id.* In light of such imprecision, three Justices complained in *Celotex* that "the Court has not clearly explained what is required of a moving party seeking summary judgment on the ground that the non-moving party cannot prove its case," and they predicted that "the Court's opinion will very likely create confusion." *Id.* at 329 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting).

This prediction was certainly accurate. Despite the clarifying opinions accompanying the majority opinion in *Celotex*,[8] the case is commonly misunderstood as holding that a conclusory

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[8] Justice White, who provided the fifth vote for the majority's result on the facts of the case, noted that "the movant must discharge the burden the Rules place upon him: It is not enough to move for summary judgment without supporting the motion in any way or with a *conclusory assertion* that the plaintiff has no evidence to prove his case." 477 U.S. at 328 (White, J., concurring) (emphasis added). The three other Justices who addressed the point observed: "If there is literally no evidence in the record, the moving party may demonstrate this by reviewing for the court the admissions, interrogatories, and other exchanges between the parties that are in the record. Either way, however, the moving party must *affirmatively* demonstrate that there is no evidence in the record to support a judgment for the nonmoving party. If the moving party has not fully discharged this initial burden of production, its motion for summary judgment must be denied, and the Court need not consider whether the moving party has met its ultimate burden of persuasion." *Id.* at 332 (Brennan, J., joined by Burger, C.J., and Blackmun, J., dissenting) (emphasis added) (citation omitted).

assertion that the other party cannot prove its case is enough to force a response, a point that the Fifth and Eleventh Circuits have both noted. *See* p. 2, *supra*. Indeed, one study of federal summary judgment opinions citing *Celotex* revealed that by and large "courts are not reviewing the sufficiency of the defendant/movant's production": in *60 percent* of cases in which summary judgment was granted, there was *no* "discussion of the sufficiency of the defendant's production in support of the summary judgment motion." Samuel Issacharoff and George Loewenstein, *Second Thoughts About Summary Judgment*, 100 YALE L.J. 73, 91-92 (1990). Even the D.C. Circuit, from which *Celotex* originated, has ignored the movant's burden in at least one case. *See ACLU Foundation of Southern California v. Barr*, 952 F.2d 457, 469 (D.C. Cir. 1991) (stating that movant "need only assert that plaintiffs do not have sufficient evidence to carry their burden of proving" the fact at issue).[9]

The widespread confusion in the lower courts over *Celotex*, and the circuit conflict it has engendered, are reason enough for this Court to grant review in order to clarify the nature of a movant's summary judgment burden. But the danger posed by the decision below to fairness and efficiency in the administration of justice is a final ground for review.

As Dean Friedenthal has observed, presumably it would be constitutionally permissible to "require a party with the burden of proof . . . to make a pretrial showing that it could support its case with some evidence," either in every case, or on the demand of the opponent. Jack H. Friedenthal, *Cases on Summary Judgment: Has There Been a Material Change in Standards?*, 63

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[9] Indeed, even the Sixth Circuit appears confused about the meaning of *Celotex*. In two decisions rendered prior to the decision below, it has applied Rule 56(c) correctly. *See Wilson v. City of Zanesville*, 954 F.2d 349, 350-51 (6th Cir. 1992) ("the movant must always bear this initial [Rule 56(c)] burden, whether or not the adverse party responds," and "the court must examine the movant's motion for summary judgment to ensure that he has discharged that burden"); *Carver v. Bunch*, 946 F.2d 451, 454-55 (6th Cir. 1991) ("the requirement that the movant bears the initial burden has remained unaltered" by *Celotex*). Both decisions were cited to the Sixth Circuit below, which inexplicably ignored them.

NOTRE DAME L. REV. 770, 772 (1988). But "[w]hether or not we would want to inaugurate such a 'put up or shut up' procedure" as a matter of policy is another question. *Id.* Permitting the Sixth Circuit and other courts to continue with their "put up or shut up" approach would be "extremely wasteful": "If one party could, merely by filing an unsupported motion, force an opponent to make a substantial showing, there would be a strong incentive to make such a filing, if for no other reason than to harass the other party and raise its costs of litigation." *Id.* at 776.[10]

After all, "[t]he purpose of summary judgment is to save courts and litigants from the burdens of trying cases where no genuine dispute exists, not to raise the stakes by meaningless procedural devices." *Id.* at 776-77. From an efficiency perspective, there appears to be ample reason to believe that the rule followed by the Sixth Circuit "will likely increase aggregate legal expenditures, thus producing a corresponding deadweight loss to society." Issacharoff and Loewenstein, *supra*, 100 YALE L.J. at 103. Regardless of how these policy issues might be resolved by Congress and the rulemakers, given the present Rule 56(c) it is clear that the Sixth Circuit and the other courts currently following the "put up or shut up" rule are misguided, and should be corrected through this Court's prompt intervention.

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[10] Another scholar has addressed the point in pragmatic terms:

> The Constitution aside, look at the practical position of plaintiffs. Something close to a one page form motion by defendant can throw on the plaintiff the responsibility to dredge, structure, collate and cross-reference all materials in the file to make them available to the judge before trial. Because the material must be reduced to a coherently structured written form, this task can sometimes take as long or longer than actually trying the case. And if this task is done with less than complete thoroughness, since the judge has no other access to the potential record material, the result will be not merely a finding that the record cannot confidentially be predicted, but the entry of judgment for the defendant.

D. Michael Risinger, *Another Step in the Counter-Revolution: A Summary Judgment on the Supreme Court's new Approach to Summary Judgment*, 54 BROOKLYN L. REV. 35, 41-42 (1988).

CONCLUSION

For all these reasons, certiorari should be granted.

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APPENDICES

APPENDIX A

Decision of the United States Court of Appeals for the Sixth Circuit, dated October 20, 1993 . . . . . **A1**

APPENDIX B

Decision of the United States District Court for the Middle District of Tennessee, dated July 31, 1992 . . . **A10**

APPENDIX C

Report and Recommendation of the United States Magistrate Judge to the United States District Court for the Middle District of Tennessee, recommending a grant of summary judgment, dated March 19, 1992 . . . **A14**

APPENDIX A

UNITED STATES COURT OF APPEALS
For the Sixth Circuit

No. 92-6172

JAMES A. ELKINS, SR.; MARY JO ELKINS; JAMES A. ELKINS, II, *Plaintiffs*, JAMES ELKINS, JR., *Plaintiff-Appellant*, v. RICHARDSON-MERRELL, INC., *Defendant-Appellee*.

On Appeal from the United States District Court for the Middle District of Tennessee.

Decided and Filed October 20, 1993

Before: GUY and NELSON, Circuit Judges; and WELLFORD, Senior Circuit Judge.

HARRY W. WELLFORD, Senior Circuit Judge. Once again this court considers a product liability action alleging that Bendectin, a drug manufactured by Richardson-Merrell, Inc., (RMI), caused a severe birth defect. The district court granted summary judgment in RMI's favor based on the similarity between this case and two recent Bendectin cases in this circuit, both of which ended in summary judgment for the defendant. *Lee v. Richardson-Merrell, Inc.*, 772 F. Supp. 1027 (W.D. Tenn. 1991), *aff'd, mem.*, 961 F.2d 1577 (6th Cir.), *cert. denied*, 113 S. Ct. 197 (1992); *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 736 F. Supp. 737 (E.D. Ky. 1990), *aff'd*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 121 L. Ed. 2d 47, 113 S. Ct. 84 (1992). The plaintiff now appeals the entry of summary judgment against him.

I.

Bendectin has been approved by the FDA for the purpose of combatting morning sickness since 1956. Faced with costly litigation involving the use of Bendectin, however, Merrell-Dow

voluntarily withdrew the drug from the market in 1983. Notwithstanding Bendectin's withdrawal from the marketplace, the FDA has maintained its support of Bendectin as a safe and effective drug for the purpose of relieving nausea and vomiting associated with pregnancy. Moreover, comparison studies have failed to detect any significant reduction in the incidence of birth defects since Bendectin became unavailable in 1983.

The proof in this case is identical to the proof offered in the two other recent Bendectin cases in this circuit--*Turpin* and *Lee*.[1] In all three cases, as in myriad Bendectin cases in other circuits, the plaintiffs rely on *in vitro* (in the test tube) studies, *in vivo* (animal) studies, and reanalyses of human epidemiological studies. The defendants, on the other hand, rely on more than 30 human epidemiological studies, all of which concluded that there was no identifiable link between Bendectin and birth defects.[2] Relying almost exclusively on *Turpin*, the magistrate

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[1] In their unsuccessful motion for consolidation, the plaintiffs asserted that:

> [d]iscovery of all of the defendant's witnesses has been essentially completed except for a few experts. In the *Lee* case and it is anticipated that the same witnesses will be utilized in the *Elkins* case. [sic.] On the other hand, all of the plaintiffs' witnesses in the *Elkins* and *Lee* cases will be the same except for some brief individual witnesses on damages and the parents.

Elkins v. Richardson-Merrell, Inc., No. 3:91-0167, slip. op. at 4. In *Lee v. Richardson-Merrell, Inc.*, 961 F.2d 1577 (6th Cir. 1992)(unpublished), slip. op. at 2-3, this court noted that "the evidence presented by the Lees in the instant case is identical in all material respects to the evidence relied upon by the plaintiffs in [*Turpin v. Merrell-Dow Inc.*, 959 F.2d 1349 (6th Cir.) *cert. denied*, 113 S. Ct. 84 (1992)]." Thus, the evidence presented in *Elkins*, *Lee*, and *Turpin* is indistinguishable in any material respect.

[2] For purposes of this case, a technical analysis of the plaintiff's proof is unnecessary. Judge Merritt engaged in a thorough analysis of the studies exploring the possible connection between Bendectin and birth defects in *Turpin*, 939 F.2d at 1353-60. A detailed analysis of the methodology behind the studies appeared in a recent Third Circuit case, *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945-49 (3d Cir. 1990).

recommended that summary judgment be issued in Merrell's favor. The district court found "no material differences" between *Elkins* and *Lee*, and, relying also on *Turpin*, accepted the magistrate's recommendation.

The plaintiff argues on appeal that under the United States Supreme Court's recent decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), the scientific opinions offered by the defendant's expert witness were inadmissible; that the defendant therefore failed to show the absence of a genuine issue of material fact; that under Tennessee law, which must be applied here pursuant to *Erie Railroad v. Tompkins*, 304 U.S. 64 (1938), it was error for the district court to take a "hard look" at the basis for the scientific theories and inferences embodied in the plaintiffs' affidavits, and that the district court violated the Seventh Amendment by failing to preserve the plaintiffs' right to trial by jury.

II.

In *Turpin v. Merrell-Dow, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992), we dealt at length with the difficult issues attending the nature of proof presented by plaintiffs in Bendectin actions like this one. In an opinion authored by Chief Judge Merritt, this court affirmed the district court's grant of summary judgment, based on the weakness of the causal link between Bendectin and birth defects. We held that:

> Based on the record before us, . . . whether Bendectin caused the minor plaintiff's birth defects is not known and is not capable of being proved to the requisite degree of legal probability based on the scientific evidence currently available. Taken in the light most favorable to the plaintiffs, the scientific evidence that provides the foundation for the expert opinion on causation in this case is not sufficient to allow a jury to find that it is more probable than not that Bendectin caused the minor plaintiff's injury.

Turpin, 959 F.2d at 1350.[3]

In Turpin, we found additional authority supporting the view of the court: *Wilson v. Merrell Dow Pharmaceuticals*, 893 F.2d 1149, 1154 (10th Cir. 1990) (finding "particularly significant" the "absence of epidemiological evidence showing a causal relationship between Bendectin and birth defects"); *Brock v. Merrell Dow Pharmaceuticals*, 874 F.2d 307, 315, (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990) (verdict for plaintiff set aside by j.n.o.v.--"we are convinced that the Brocks did not present sufficient evidence regarding causation to allow a trier of fact to make a reasonable inference that Bendectin caused Rachel Brock's limb reduction defect"). We also considered *Daubert v. Merrell Dow Pharmaceuticals*, 951 F.2d 1128 (9th Cir. 1981), and *DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d 941 (3d Cir. 1990), in *Turpin*.

We construe *Turpin* to treat the plaintiff's expert opinion indicating a basis of support for the plaintiffs' theories in animal studies to be admissible but "simply inadequate . . . [to] permit a jury to conclude that Bendectin more probably than not causes limb defects." *Id.* at 1360. This court found the evidence to be admissible, we believe, but that it presented too wide an "analytical gap" for reasonable inferences on causation "to be drawn on the ultimate issue of human birth defects." *Turpin*, 959 F.2d at 1360. As we have already indicated, the evidence offered by *Elkins* does not differ in any material respect from evidence presented in both *Turpin* and *Lee*. We agree with the district court that this case is factually indistinguishable from *Turpin* and *Lee*. Thus, unless the plaintiffs have demonstrated some reason,

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[3] In *Turpin* and in *Lee*, seven different judges sitting on this court have adhered substantially to this view expressed by Chief Judge Merritt. The panel in this case consists of three additional Sixth Circuit judges. We do not count in this number the three different additional judges on this court who considered and affirmed the class action jury verdict for the defendant on the issue of causation of human birth defects by ingestion of Bendectin. *In re Bendectin Litigation*, 857 F.2d 290 (6th Cir. 1988), *cert. denied sub. nom. Hoffman v. Merrell Dow Pharmaceuticals, Inc.*, 488 U.S. 1006, (1989).

aside from any factual argument, why those cases should not apply here, *Turpin* and *Lee* control this case, and mandate summary judgment in Merrell's favor.

A.

The plaintiff argues that, considering the Supreme Court's recent decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), the defendants failed to meet their burden, under Rule 56(c), of showing, "that there is no genuine issue as to any material fact and that [Merrell] is entitled to a judgment as a matter of law." Fed R. Civ. P. 56(c). Under *Daubert*, the plaintiffs contend, the only affidavit used to support the defendant's motion for summary judgment has not been shown admissible. Thus, the plaintiffs argue that summary judgment must be reversed, or in the alternative, that remand is necessary, so the district court may determine, consistent with *Daubert*, whether the defendant's affidavit is admissible.

The plaintiff has misinterpreted the defendant's burden regarding summary judgment. Because Merrell does not bear the ultimate burden of persuasion on the causation issue, Merrell need only point out the lack of a genuine issue regarding causation. *See, Calderone v. United States*, 799 F.2d 254, 259 (6th Cir. 1986)("when the moving party does not have the burden of proof on the issue, he need show only that the opponent cannot sustain his burden at trial.") Moreover, Merrell had no obligation to support its motion for summary judgment with *any* affidavits. Rule 56 provides that a defending party may "move *with or without supporting affidavits* for summary judgment in the party's favor." Fed. R. Civ. P. 56(b) (emphasis added). As the Supreme Court has explained,

> regardless of whether the moving party accompanies its summary judgment motion with affidavits, the motion may, and should, be granted so long as whatever is before the district court demonstrates that the standard for the entry of summary judgment, as set forth in Rule 56(c) is satisfied.

Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

Merrell pointed out the absence of a genuine factual issue on the material element of causation. The district court agreed that the plaintiffs had failed to establish a genuine factual dispute regarding causation. In doing so, the court relied on *Turpin*, where this court determined that, even

> [t]aken in the light most favorable to the plaintiffs, the scientific evidence that provides the foundation for the expert opinion on causation in this case is not sufficient to allow a jury to find that it is more probable than not that Bendectin caused the minor plaintiff's injury."

Turpin, 959 F.2d at 1350. The reason for summary judgment was not the strength of the defendant's proof, but the insufficiency of the plaintiffs' proof. Thus, the admissibility of Merrell's affidavit under *Daubert* is irrelevant; the district court properly determined that the *plaintiffs* failed to demonstrate the existence of a genuine factual dispute regarding causation. The plaintiffs bear the burden of establishing causation. As a result, *Daubert* does not invalidate the district court's summary judgment analysis in this case.

B.

Even though the plaintiff concedes that he relies on "evidence similar to that found in *Turpin* and *Lee*," he argues that Tennessee law, not federal law, is controlling under *Erie Railroad v. Tompkins*, 304 U.S. 64 (1938), and specifically, that this court adopts state law when ruling on summary judgment motions in diversity cases, citing *McDonald v. Union Camp Corp.*, 898 F.2d 1155, 1163 (6th Cir. 1990), and *Bank of Cumberland v. Aetna Casualty Co.*, 956 F.2d 595, 597 (6th Cir.), *cert. denied*, 113 S. Ct. 204 (1992), among others.[4] They contend that *Turpin*'s instruction to take a "hard look" at the

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[4] While we are merely reciting the plaintiffs' argument here, we note that the cases relied upon by the plaintiffs in their brief as to the sufficiency of the evidence deal with directed verdicts and judgments notwithstanding the verdict, not summary judgment.

basis for scientific opinions is at odds with Tennessee law regarding summary judgment. *See Turpin*, 959 F.2d at 1352. Consequently, they argue, the district court violated the *Erie* doctrine by relying on *Turpin*.

The defendant responds that the plaintiff has failed to raise this issue prior to appeal. In Elkins' objections to the magistrate judge's recommendation that summary judgment be granted to the defendant, the plaintiff mentioned: (1) "the Seventh Amendment;" (2) "all of the Rules of Evidence;" (3) a petition for certiorari pending in *Turpin*; (4) confusion of the "issue of res judicata and collateral estoppel with stare decisis;" (5) "lack of wisdom of the Opinion in *Turpin*;" (6) "all of the science that is involved [should be considered] in order to reach a conclusion;" (7) defendant's drug is a teratogen, and . . . caused the defect in this case;" (8) methodology of the parties' experts is the same; and (9) "only the conclusions of the experts differ." Conspicuous by its absence from this list was any mention of state law evidential requirements as to the summary judgment, or any mention of *Erie Railroad* requirements. Moreover, the district judge mentioned nothing in his memorandum opinion overruling the plaintiff's objections about applying state law or *Erie Railroad*. The plaintiffs sought no reconsideration or clarification of this decision based upon the district court's overlooking any argument such as is now advanced. This court does not normally address issues raised for the first time on appeal. *Taft Broadcasting Co. v. United States*, 929 F.2d 240, 243-45 (6th Cir. 1991); *White v. Anchor Motor Freight, Inc.*, 899 F.2d 555, 559 (6th Cir. 1990). While this rule is discretionary, the court has adhered to the rule except in "'exceptional cases or particular circumstances' or when the rule would produce 'a plain miscarriage of justice.'" *Pinney Dock and Transp. Co. v. Penn Cent. Corp.*, 838 F.2d 1445, 1461 (6th Cir.) *cert. denied*, 488 U.S. 880 (quoting *Hormel v. Helvering*, 312 U.S. 552, 557-58 (1941)). This case does not present the kind of exceptional circumstances that warrant disregarding the general rule. Because the plaintiffs did not adequately raise the *Erie Railroad* argument before the district court, we decline to consider that issue for the first time on appellate review.

C.

The plaintiff's final argument is that *Turpin* requires a court to weigh the credibility of the evidence when ruling on a summary judgment motion, and that this practice violates the Seventh Amendment right to a jury trial. We disagree.

Noting the "difficulty . . . in knowing what reasonable inferences of causation to draw from animal experiments and epidemiological studies" and the "uncertainty of judges about how far they should enter the scientific thicket of conflicting inferences in order to determine whether the basis of a scientific opinion concerning causation is significantly plausible to allow a jury to ground a verdict on it," Judge Merritt's opinion in *Turpin* instructed district judges to take a "hard look" at the basis of scientific opinions. *Turpin*, 959 F.2d at 1352. The court held that "close judicial analysis of . . . technical and specialized matter" is necessary not only to control juror misunderstanding, but also to curtail "the potential for exaggeration and fraud on the court, [which is often] impossible to discover without close inspection and careful consideration of the record." *Id.* at 1352-53.

The direction to take a "hard look" at the basis of a scientific opinion does not require weighing credibility any more than the Supreme Court's direction to consider the record as a whole and decide whether any rational juror could decide the disputed factual issue in the plaintiff's favor. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (summary judgment is appropriate "where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party"); *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1480 (6th Cir. 1989) (same). Moreover, the Supreme Court recently cited *Turpin* with approval as a preferred method of dealing with weak scientific proof in Bendectin cases. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2798 (1993). Significantly, the Court in *Daubert* indicated that even if expert opinion or evidence on one side were relevant and admissible, if "insufficient to allow a reasonable juror to conclude that the position more likely than not is true," it may be the basis for a directed verdict or a grant of summary judgment.

Id. at 8. Following this last observation, the Court added:

> *Cf.*, e.g., *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (CA6) ("holding that scientific evidence that provided foundation for expert testimony, viewed in the light most favorable to plaintiffs, was not sufficient to allow a jury to find it more probable than not that defendant caused plaintiff's injury), *cert. denied*, 506 U.S. 1992); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (CA5 1989) (reversing judgment entered on jury verdict for plaintiffs because evidence regarding causation was insufficient), *modified*, 884 F.2d 166 (CA5 1989), *cert. denied*, 494 U.S. 1046 (1990). . . ."

Id. at 9. Thus, we do not believe that the prophylactic measure adopted in *Turpin* violates the Seventh Amendment.

III.

As we have repeatedly indicated, we agree with the district court that this case is indistinguishable from *Turpin* and *Lee*, both factually, and regarding the scientific evidence presented. We deem that *Daubert* does not require a remand for the reasons herein pointed out. Because the plaintiffs did not adequately raise the *Erie Railroad* argument before the district court, we decline to consider that issue for the first time on appeal. Finally, we do not believe that the *Turpin* hard look analysis violates the Seventh Amendment. Consequently, the plaintiff has failed to demonstrate any reason why reliance on *Turpin* and *Lee* as controlling precedent is improper. For the reasons we have indicated, then, we **AFFIRM** the district court.

APPENDIX B

UNITED STATES DISTRICT COURT
For the Middle District of Tennessee
Nashville Division

No. 3:91-0167
Judge Higgins

JAMES ALBERT ELKINS, SR., et al.
v. RICHARDSON-MERRELL, INC.

July 31, 1992

MEMORANDUM

The Court has before it the Report and Recommendation of the Magistrate Judge (entered March 19, 1992; Docket Entry No. 31), the plaintiff's objections thereto (filed April 7, 1992; Docket Entry No. 33), and the defendant's response to the plaintiff's objections (filed April 15, 1992; Docket Entry No. 35). After having reviewed the entire record, and for the reasons stated below, the Court adopts and approves the Report and Recommendation in all regards. The plaintiff's objections are overruled. Therefore, the defendant's motion for summary judgment (filed June 24, 1991; Docket Entry No. 14) shall be granted.

I. DISCUSSION

This action was filed by James Albert Elkins, Sr., and Mary Jo Elkins, individually and as parents and natural guardians of James Albert Elkins, II. The plaintiffs allege that Mary Jo Elkins took the prescription drug Bendectin, which was manufactured by the defendant, to treat the symptoms of morning sickness while pregnant. They further allege that James Elkins, II, was born with severe birth defects because of his mother's ingestion of Bendectin while pregnant.

The claims of the plaintiffs, James Elkins, Sr., and Mary Jo Elkins, were dismissed with prejudice by stipulation. *See* stipulation of dismissal (entered May 17, 1991; Docket Entry

No. 7); Order (entered June 27, 1991; Docket Entry No. 18). Therefore, only the claims of James Elkins, II, remain. The defendant Merrell filed its motion for summary judgment on June 24, 1991 (Docket Entry No. 14), arguing that

> there is no admissible evidence sufficient to raise a triable issue of fact as to whether Bendectin is capable of causing birth defects. Since plaintiff cannot establish that Bendectin is capable of causing birth defects in general, he cannot, as a matter of law, establish that Bendectin was a proximate cause of his birth defects.

Memorandum of law in support of defendant Merrell Dow's[1] motion for summary judgment at 3 (filed June 24, 1991; Docket Entry No. 16).

The Magistrate Judge recommended granting Merrell's motion for summary judgment, based on the similarities between this case and the recently decided case of *Turpin v. Merrell-Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir., 1992). Report and Recommendation at 2-3. In *Turpin*, the Sixth Circuit Court of Appeals exhaustively discussed the wealth of scientific studies, proffered by both parties, which have been performed to determine whether Bendectin causes birth defects. *See Turpin*, 959 F.2d 1349, 1353-1359. The Court of Appeals affirmed the decision of the district court to grant summary judgment for the defendant, concluding that

> the plaintiffs' experts stop short of testifying that Bendectin more probably than not caused the birth defects in babies. They stop short because they have no factual or theoretical basis for a stronger hypothesis.
>
> . . . .
>
> The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide. Under such circumstances, a

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[1] Merrell-Dow has changed its name to Richardson-Merrell and will be referred to as "Merrell" throughout this memorandum.

> jury should not be asked to speculate on the issue of causation.

Id., at 1349. Thus, the Court did not rule out the possibility that Bendectin may be proven to cause birth defects in humans. It merely concluded that the evidence before it was not sufficient to allow the jury to decide the issue of causation. *See id.* 959 F.2d 1349, slip op. at 22.

Similarly, in *Lee v. Richardson-Merrell*, No. 91-5369 (6th Cir., April 22, 1992) (unpublished disposition), another panel of the Sixth Circuit affirmed the district court's grant of summary judgment in favor of the defendant, concluding "that a finding of a causal relationship between Bendectin use and [the injured plaintiff's] birth defects based upon this evidence would be conjectural at best in light of this court's recent opinion in [*Turpin*]." *Id.*, slip op. at 3. The *Lee* case is virtually identical to this case. In the memorandum in support of the motion to consolidate the two cases, the plaintiffs stated that "the complaints [in the *Lee* and *Elkins* cases] are nearly identical in substance. . . ." Memorandum of points and authorities in support of plaintiffs' motion to consolidate at 1, filed as exhibit 1 to the supplement to the memorandum in support of Merrell's motion for summary judgment (filed May 12, 1992; Docket Entry No. 36). The plaintiffs also asserted as grounds for consolidation that

> [d]iscovery of all of the defendant's witnesses has been essentially completed except for a few experts. In the *Lee* case and it is anticipated that the same witnesses will be utilized in the *Elkins* case. [Sic.] On the other hand, all of the plaintiffs' witnesses in the *Elkins* and *Lee* cases will be the same except for some brief individual witnesses on damages and the parents.

Id. at 2. Given the admitted similarity between the *Lee* case and this case, and having found no material differences in the two cases during its own review, the Court grants Merrell's motion for summary judgment.

II. CONCLUSION

For the reasons stated above, the Court adopts and approves the Magistrate Judge's Report and Recommendation in all regards. Therefore, the defendant's motion for summary judgment shall be granted.

An appropriate order shall be entered.

(signed)_____
Thomas A. Higgins
United States District Judge
July 31, 1992

ORDER

In accordance with the memorandum contemporaneously entered, the Report and Recommendation of the Magistrate Judge (entered March 19, 1992; Docket Entry No. 31) is adopted and approved in all regards. The plaintiff's objections thereto (filed April 7, 1992; Docket Entry No. 33) are overruled.

Therefore, the defendant's motion for summary judgment (filed June 24, 1991; Docket Entry No. 14) is granted. All issues before the Court having been disposed on their merits, this case is dismissed with prejudice.

It is so ORDERED.

(signed)_____
Thomas A. Higgins
United States District Judge
July 31, 1992

APPENDIX C

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

No. 3:91-0167
Judge Higgins

JAMES ALBERT ELKINS, SR., et al.
v. RICHARDSON-MERRELL, INC.

March 19, 1992

REPORT AND RECOMMENDATION

I. INTRODUCTION

This civil action was referred to the Magistrate Judge by the Honorable Thomas A. Higgins, District Judge by Order entered August 9, 1991 (Docket Entry No. 25). Pursuant to 28 U.S.C. § 636(b)(1)(B), the Magistrate was directed to consider, submit proposed findings of fact and make recommendations for disposition as to the following motion. Pending before the Court is defendant's motion for summary judgment (Docket Entry No. 14).

Plaintiffs, James Elkins, Sr. and Mary Jo Elkins, individually and as parents and guardians of James Albert Elkins II, Tennessee citizens, filed this action under 28 U.S.C. § 1332, the federal diversity statute, against defendant Merrell Dow Pharmaceuticals, Inc. (formerly Richardson-Merrell, Inc. and hereinafter "Merrell"), a Delaware corporation with its principal place of business in Ohio. Merrell manufactured and sold the drug Bendectin from 1956 to 1983. Bendectin is designed to treat the "morning sickness" which pregnant women suffer. Mary Jo Elkins took this drug while carrying plaintiff James Albert Elkins II ("Elkins"). Elkins was subsequently born with severe birth defects.

On October 31, 1991, the Magistrate recommended that consideration of the pending motion be stayed pending the Court of Appeals' ruling on an appeal from *Turpin v. Merrell Dow Pharmaceuticals*, 736 F.Supp. 737 (E.D. Ky. 1990). (Docket Entry No. 29). On January 28, 1992, the Court adopted this recommendation. (Docket Entry No. 30).

On March 11, 1992, the Court of Appeals affirmed summary judgment for Merrell. *See Turpin v. Merrell Dow Pharmaceuticals, Inc.*, No. 90-5690 (6th Cir., March 11, 1992) (*slip op.*) (a copy of which is attached hereto). The Court of Appeals held that epidemiological evidence was not conclusive on the issue of causation. *Id.* at 17. On the other hand, the Court of Appeals considered plaintiff's evidence and concluded that "the factual and theoretical bases articulated for the scientific opinions stated will not support a finding that Bendectin more probably than not caused the birth defect here." *Id.* at 22. The Court of Appeals held that the animal studies relied upon by plaintiff's experts did not prove causation in humans.

> Here, the record's explanation of the animal studies is simply inadequate. Although the animal studies themselves may have been scientifically performed, the exact nature of these tests is explained only in general terms. The record fails to make clear why the varying doses of Bendectin or doxyalamine succinate given to the rats, rabbits and *in vitro* animal cells would permit a jury to conclude that Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy. The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation.

Id. at 24.

The Magistrate notes that the evidence submitted in *Turpin* is virtually identical to the evidence in this action. The *Turpin* plaintiff also suffered limb deformities in circumstances which are similar to the ones at issue here. *See id.* at 3.

Accordingly, the Magistrate recommends that Merrell's motion for summary judgment be granted. If there are any meaningful distinctions between the present case and *Turpin*, the parties may raise them in their objections to this Report and Recommendation. The Magistrate further recommends that if such objections are made that the Court should remand this action to the Magistrate for further consideration. Under Rule 72(b) of the Federal Rules of Civil Procedure, any party has ten (10) days from receipt of this Report and Recommendation in which to file any written objections to this Recommendation, with the District Court. Any party opposing said objections shall have ten (10) days from receipt of any objections filed to this Report in which to file any responses to said objections. Failure to file specific objections within ten (10) days of receipt of this Report and Recommendation can constitute a waiver of further appeal of this Recommendation. *Thomas v. Arn*, 474 U.S. 140, 106 S.Ct. 466, 88 L.Ed.2d 435 (1985), *reh'g denied*, 474 U.S. 1111 (1986).

Entered this the 19th day of March, 1992.

(signed)
WILLIAM J. HAYNES, JR.
United States Magistrate Judge